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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	10-28-98
Publication Date	10-29
Certifier	J. Borlino

Food and Drug Administration

Biological Response Modifiers Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Biological Response Modifiers Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 13, 1998, 8 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail M. Dapolito or Rosanna L. Harvey, Center for Biologics Evaluation and Research (HFM-21), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0314 or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12389. Please call the Information Line for up-to-date information on this meeting.

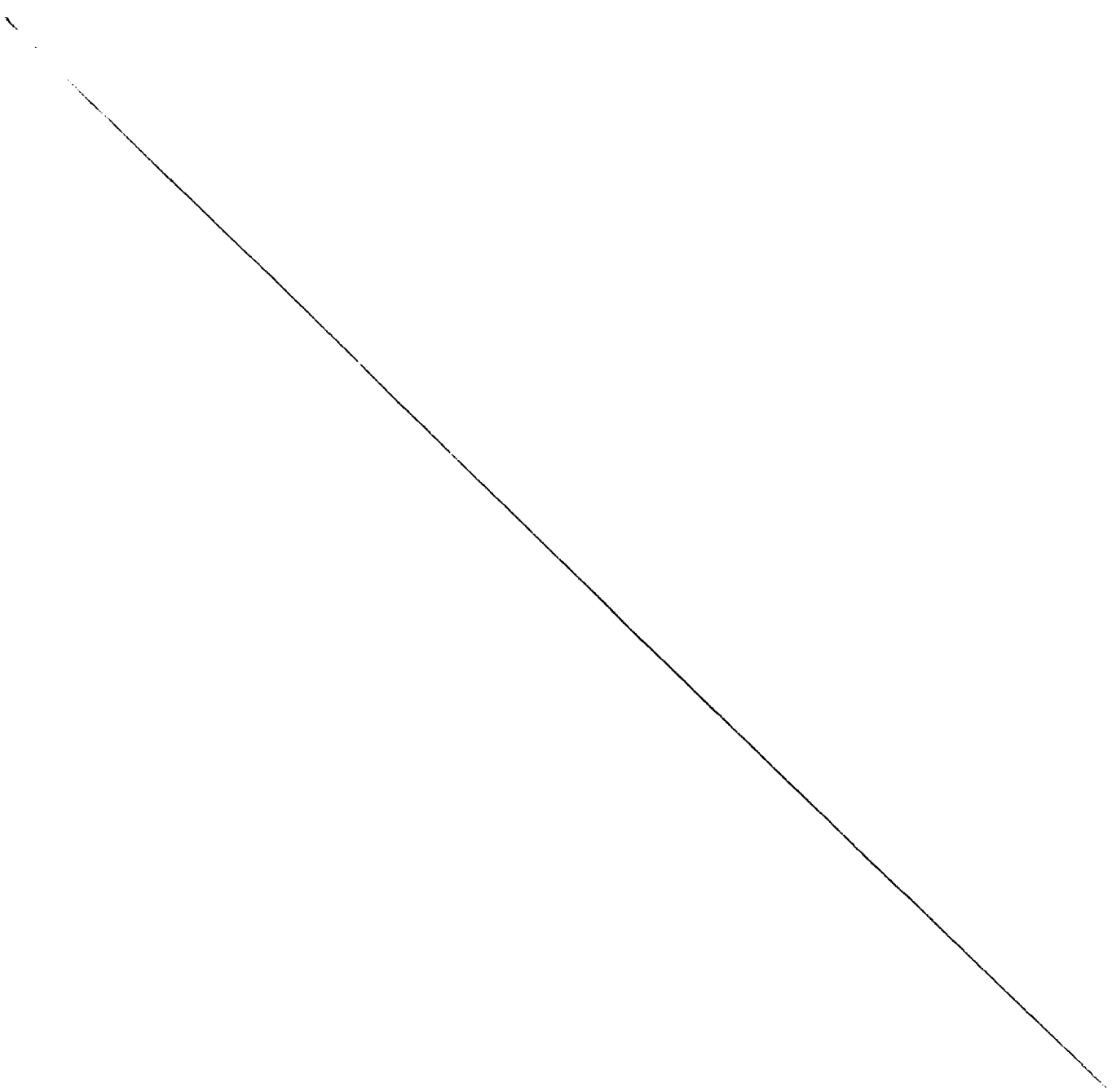
Agenda: The committee will participate in a general scientific discussion of allogeneic transplantation with a focus on haplo-identical transplantation and other high risk transplantations.

Procedure: On November 13, 1998, from 8:30 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 6, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. Time allotted for each presentation may be limited. Those desiring to

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make formal oral presentations should notify the contact person before November 6, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On November 13, 1998, from 8 a.m. to 8:30 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). This portion of the meeting will be closed to discuss issues related to past and pending biologics license applications and investigational new drug applications.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.
2).

Dated: October 22, 1998

MA Friedman

Michael A. Friedman
Deputy Commissioner for Operations

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

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Orla Bowers